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CONCORDIA PHARMACEUTICALS, INC., Plaintiff, v. METHOD PHARMACEUTICALS, LLC, et al., Defendants.

Civil Action No. 3:14CV00016

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA, CHARLOTTESVILLE DIVISION

2016 U.S. Dist. LEXIS 50221

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PRIOR HISTORY: *Concordia Pharms., Inc. v. Method Pharms., LLC, 2015 U.S. Dist. LEXIS 151505 (W.D. Va., Nov. 4, 2015)*

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JUDGES: Hon. Glen E. Conrad, Chief United States District Judge.

OPINION BY: Glen E. Conrad

OPINION

MEMORANDUM OPINION

In this action under the Lanham Act, the plaintiff, Concordia Pharmaceuticals, Inc. ("Concordia"), and the defendants, Method Pharmaceuticals, Inc. and Matthew Scott Tucker (collectively, "Method"), have moved to exclude certain opinions offered by the opposing side's expert witnesses. The court held a hearing on the motions on March 3, 2016.[1] This memorandum opinion sets forth the court's rulings on the parties' motions.

1 During the March 3, 2016 hearing, the court also heard oral argument on the parties' cross-motions for summary judgment. On March 29, 2016, Concordia's motion for summary judgment was denied, and Method's motion for summary judgment was granted in part and denied in part. The case is proceeding to trial solely on Concordia's claim under the Lanham Act.

Background

The facts of this case are outlined [*3] in detail in the court's memorandum opinion on the parties' cross-motions for summary judgment. Thus, only a brief summary follows here.

In May of 2014, Concordia acquired the Donnatal® line of products ("Donnatal") from PBM Pharmaceuticals, Inc. ("PBM"). Donnatal is a line of combination phenobarbital and belladonna alkaloid ("PBA") products that is used as adjunctive therapy in the treatment of irritable bowel syndrome ("**IBS**") and acute enterocolitis. Donnatal is available by prescription in either tablet or elixir form.

Donnatal was first introduced in the 1930s, before drug manufacturers were required to prove that drugs were both safe and effective in order to obtain approval by the Food and Drug Administration ("FDA"). Although Donnatal products have been approved for safety, the FDA has yet to determine their effectiveness.

For over thirty years, Donnatal faced competition from generic PBA products that were pharmaceutically equivalent to Donnatal. Beginning in August of 2011, manufacturers of the generic versions began to take their products off the market. Once the inventories of previously manufactured generic products were eliminated, Donnatal was the only line of PBA products [*4] available for prescription.

In 2013, Method began making plans to develop and market a new product that would be pharmaceutically equivalent to Donnatal. The new product was eventually named Me-PB-Hyos. Method reached out to Winder Laboratories, LLC ("Winder"), which had previously developed another product for Method, and expressed an interest in having Winder manufacture its Me-PBHyos products. Winder and Method agreed on the price that Winder would charge for supplying the products, and Method issued purchase orders for initial stability tests.

In March of 2014, Method used publicly-available copies of the Donnatal product labels and package inserts as templates to create labels and inserts for the Me-PB-Hyos products. Method then proceeded to list the Me-PB-Hyos products with two pharmaceutical databases, Medi-Span and First Databank, which are used by members of the pharmaceutical industry to determine whether generic substitutes are available for brand name products. Method advised the databases that it intended to start marketing the Me-PB-Hyos products on June 1, 2014. Based on the information provided by Method, which included the product labels and package inserts, the Me-PB-Hyos [*5] products were assigned the same Generic Product Identifier ("GPI") as Donnatal. The listings also indicated that the Me-PB-Hyos products would be available at a lower price.

Ultimately, after this litigation ensued, Method halted its plans to market the Me-PBHyos products, and the products were never manufactured by Winder or any other company. In mid-October 2014, Medi-Span removed the listings for the Me-PB-Hyos products. Around the same time, First Databank moved its listings for the Me-PB-Hyos products from active listings to archived listings.

After Method's Me-PB-Hyos products were listed with Medi-Span and First Databank, Donnatal prescriptions and unit sales declined. The parties dispute, however, whether the decline in prescriptions and unit sales was caused by the listings for the Me-PB-Hyos products.

From January of 2012 to June 2014, the prices of Donnatal products increased by over 1,400%. This included a 100% increase that Concordia implemented after acquiring the rights to Donnatal from PBM. It is undisputed that Concordia's profits and profit margin for Donnatal tablets and elixir increased after Method's Me-PB-Hyos products were listed with the databases. However, Concordia [*6] claims that its profits would have been even higher if Method had not listed the Me-PB-Hyos products and, thus, that it experienced lost profits as a result of the listings.

Procedural History

PBM commenced this action against Method on April 29, 2014, asserting claims of false advertising and unfair competition under the Lanham Act and related claims under state law. Following a series of amendments, the case is now being pursued against Method and Tucker, Method's founder and president, by. Concordia.

Following the completion of discovery, the parties filed cross-motions for summary judgment. On March 29, 2016, Concordia's motion for summary judgment was denied and Method's motion for summary judgment was granted in part and denied in part. A jury trial on the remaining claims under the Lanham Act is scheduled to begin on April 18, 2016.

The case is now before the court on the parties' motions to exclude opinions proffered by the opposing side's expert witnesses. Method seeks to exclude certain opinions of Dr. Brian Reisetter and Ivan Hofmann. Concordia seeks to exclude certain opinions of Dr. William Fassett and John Wills. Dr. Reisetter and Dr. Fassett are pharmacists who were retained [*7] to offer opinions regarding the database listings for Method's Me-PB-Hyos products. Hofmann and Wills are certified public accountants who were retained to offer opinions pertaining to damages.

Standard of Review

The admissibility of expert witness testimony is governed by *Rule 702 of the Federal Rules of Evidence.* The rule provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Under this rule, the district court acts as a gatekeeper to ensure that an expert's testimony "is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).* "The rule 'requires that the [expert] testimony must be the product of reliable principles and methods that are reliably applied to the facts of the case.'" *United States v. Wilson, 484 F.3d 267, 274 (4th Cir. 2007)* (quoting *Fed. R. Evid. 702* advisory committee's note). In conducting its gatekeeping function, the [*8] court's primary goal is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999).* The scope of the court's gatekeeping inquiry ultimately "depend[s] upon the particular expert testimony and facts of the case." *EEOC v. Freeman, 778 F.3d 463, 466 (4th Cir. 2015)* (citing *Kumho, 526 U.S. at 150*).

The party proffering the expert testimony has the burden of establishing its admissibility by a preponderance of the evidence. *Daubert, 509 U.S. at 593*

n.10; see also *Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001)*. In deciding whether a party has sustained its burden, the court must focus on the principles and methodology employed by the expert rather than the expert's ultimate conclusions. *Daubert, 509 U.S. at 595*. As the Supreme Court has recognized, however, "conclusions and methodology are not entirely distinct from one another." *General Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)*. Neither Daubert nor *Rule 702* requires the court "to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Id. Instead, the court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered," and accordingly choose to exclude the opinion. Id.

Of course, "the court need not determine [*9] that expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct." *United States v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006)*. "As with all other admissible evidence, expert testimony is subject to being tested by `[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' Id. (quoting *Daubert, 509 U.S. at 596*). However, because "expert witnesses have the potential to be both powerful and quite misleading," the court must ensure that any all expert testimony is both relevant and reliable. *Cooper, 259 F.3d at 199* (internal citations and quotation marks omitted).

Discussion

I. Dr. Reisetter

Concordia retained Dr. Brian Reisetter to offer opinions on the market impact and industry consequences of Method's submissions to Medi-Span and First Databank. Dr. Reisetter is a licensed pharmacist with a doctorate in pharmacy administration, who also works as a consultant for the pharmaceutical and medical industries. He has performed extensive research concerning the effects of pharmaceutical database listings on the perceptions and behavior of pharmacists and doctors. In the instant action, Dr. Reisetter has offered the opinion that Method's efforts to list its Me-PB-Hyos products with Medi-Span and First Databank "caused [*10] the marketplace to believe that there was an actual 'generic' or pharmaceutical equivalent for Donnatal appropriate for substitution," and that this "set off a series of inevitable downstream events in the marketplace that adversely affected the number of prescriptions for Donnatal filled and units sold, despite no such product being available." Reisetter Rep. ¶ 1.

In moving to exclude Dr. Reisetter's opinions on the market impact and industry consequences of Method's submissions to the pharmaceutical databases, Method questions the reliability and relevance of his opinions. Specifically, Method argues that Dr. Reisetter was not provided with full information regarding "availability issues" that were experienced with Donnatal products; that Dr. Reisetter improperly utilized Prozac as an example to explain how generic substitution occurs when a generic drug is linked to a brand drug in a pharmacy software system based on the products' GPI code; and that Dr. Reisetter improperly relied upon surveys conducted in other cases in forming his opinions in the instant case.

Having considered the parties' arguments, the court concludes that none of the issues identified by Method warrants the [*11] exclusion of Dr. Reisetter's testimony. To the extent Method faults Dr. Reisetter for not considering certain discrete "availability issues" that it identified during discovery, such as emails indicating that some pharmacies had incorrect or outdated National Drug Code ("NDC") numbers for Donnatal products, there is no indication that these issues were raised during Dr. Reisetter's deposition or considered by Method's own experts in rendering their opinions. While the availability issues identified by Method could arguably affect the weight accorded to Dr. Reisetter's testimony, the court is unable to conclude that they render his testimony inadmissible. Instead, these issues, and any effect that they may have on Dr. Reisetter's opinions, can be adequately addressed on cross-examination.

The court also declines to preclude Dr. Reisetter from using Prozac to illustrate how generic substitution commonly occurs in the pharmaceutical industry. In his report, Dr. Reisetter did not suggest that Prozac and Donnatal are similarly situated drugs. Instead, he merely used Prozac as an example to explain how generic substitution occurs when a generic drug is linked to a brand drug in a pharmacy [*12] software system based on the information contained in the pharmaceutical database listings. Method correctly points out that Prozac and the generic versions of fluoxetine are distinguishable from the products at issue in this case on a number of grounds. However, the court ultimately agrees with

Concordia that these distinctions go to the weight of Dr. Reisetter's testimony regarding generic substitution rather than its admissibility.

Finally, the fact that Dr. Reisetter based his opinions, at least in part, on surveys performed in connection with other cases or research projects does not justify excluding Dr. Reisetter's testimony. While the court may ultimately limit the extent to which Dr. Reisetter is permitted to reference specific responses to survey questions, the court will permit him to offer opinion testimony based on the results of the prior surveys. See *Fed. R. Evid. 703* ("If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted."). The defendants remain free to cross-examine Dr. Reisetter about the particular questions posed in his prior surveys, the specific [*13] populations of pharmacists surveyed, and the conclusions that he ultimately reached. The defendants are also free to point out that Dr. Reisetter's opinions are not based on quantitative or qualitative research employed to determine actual market behavior in response to the particular database listings at issue in this case. However, the court will not preclude Dr. Reisetter from offering opinions informed by surveys conducted in previous cases.[2]

2 Because the prior surveys conducted by Dr. Reisetter did not account for the actual allegations in this case, Method correctly points out that the survey results would not support a false advertising claim based on a theory of implied falsity. See *PBM Prods., LLC v. Mead Johnson & Co., 639 F.3d 111, 122 (4th Cir. 2011)* ("Because the surveys failed to account for the actual allegations in the case, they failed to provide the required evidence of [implied] falsity."). Nonetheless, this does not render Dr. Reisetter's opinions inadmissible. Concordia's false advertising claim does not turn on proof of implied falsity. Instead, Concordia maintains that Method made literally false statements regarding its Me-PB-Hyos products. Moreover, as other courts have previously recognized, an expert's "data and testimony need not [*14] prove the plaintiffs' case by themselves; they must merely constitute one piece of the puzzle that the plaintiffs endeavor to assemble before the jury." *City of Tuscaloosa v. Harcros Chems.,Inc., 158 F.3d 548, 564-65 (11th Cir. 1998).*

For these reasons, Method's motion to exclude the opinions and testimony of Dr. Reisetter will be denied.

II. Dr. Fassett

Method retained Dr. William Fassett to review the reports from Concordia's experts, and to offer his own opinions regarding market conditions applicable to the sale of Donnatal products and the effect of the database listings for Method's Me-PB-Hyos products. Dr. Fassett has been a licensed pharmacist for over 45 years and is a professor emeritus of pharmacotheraphy at Washington State University. His career has involved the traditional practice of pharmacy, as well as pharmaceutical sales and marketing, pharmacy management, and advising formulary committees with respect to drug coverage decisions. Dr. Fassett also sits on the editorial board of several peer-reviewed publications related to pharmacy and the pharmaceutical industry, and has authored peer-reviewed publications relating to drug use review, product selection, and computer applications in the pharmaceutical industry.

Concordia seeks to exclude three opinions [*15] expressed in Dr. Fassett's expert report. The first opinion challenged by Concordia pertains to drug price increases. In his report, Dr. Fassett opined that price increases are not uncommon in the pharmaceutical industry; that the ultimate reactions of pharmacists and prescribers to price increases are generally consistent; and that he would expect formularies to eventually exclude Donnatal, and prescriptions for Donnatal to ultimately decrease, in response to increased prices. Dr. Fassett cited the prescription pain reliever Vivomo as an example of this principle in operation. Vivomo, like Donnatal, currently has no generic equivalent. According to Dr. Fassett's report, the manufacturer increased the price of Vivomo by over 600%, beginning on January 1, 2014. Subsequent to the price increases, Vivomo experienced increased sales dollars, fewer prescriptions and unit sales, exclusion from formularies, and substitution, "all of which," according to Dr. Fassett, "would be expected with Donnatal." Fassett Rep. ¶ 91.

The second opinion challenged by Concordia is Dr. Fassett's opinion that a class review may have affected the formulary status of Donnatal. In his report, Dr. Fassett explained [*16] that "low-claim-volume products like Donnatal (with an average of between 7,000 and 12,000

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